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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/521,742	03/09/2000	Lars Hammarstrom	49122	2762

7590

01/02/2002

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 01/02/2002 12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/521,742

Applicant(s)

HAMMARSTROM ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 1-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Response to Amendment

1. Claims 1-46 are pending.
Claim 28 has been amended.
Claims 1-27, drawn to non-elected inventions are withdrawn from examination.
Claims 28-46 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

3. The rejection of claims 28 and 29 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn. Specifically, the rejections made in Paper number 8, page 5, paragraph 5, subsections a and b are no longer.

Maintained Rejections***Claim Rejections - 35 U.S.C. § 112***

4. The rejection of claims 28-46 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating malignant cancer cell lines such as those listed in Table 1 of the specification (page 26) comprising an enamel matrix derivative, namely EMDOGAIN®, does not reasonably provide enablement for a method for preventing or treating malignant or benign neoplasms, comprising administering to a mammal an active enamel substance is maintained. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice and implement the invention commensurate in scope with these claims.

Applicants have submitted two articles (Supplemental IDS, Paper number 10) to support their argument of no need of a "normal" cell lines. The Examiner has reviewed these articles. Applicants state, "there is no such thing as a single suitable design or set-up for any given scientific experiment." Furthermore, Applicants assert that controls studies were implemented in the instant invention and findings reported in Lyngstadaas et al. (J. Clinical Periodontology 28:181-188, 2001) support Applicants arguments. Applicants' arguments have been considered, but found unpersuasive.

Lyngstadaas' set of experiments ^{do} ~~does~~ not parallel Applicants' instant invention. Lyngstadaas investigated the mechanisms for EMD induced regeneration of periodontal tissues utilizing periodontal ligament cells and epithelial cells in the presence of EMD and monitored cellular attachment rate, proliferation, DNA replication and metabolism.

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These cell lines were grown upon EMD. The instant invention does utilize EMD as a matrix to grow upon, but the reference does not suggest that EMD has apoptotic properties or will reduce the risk of migration or recurrence of an epithelially derived tumor or neoplasm. Contrary to Applicants' arguments, scientific experiments are optimally designed to incorporate a set of controls that will further lend credence to conclusions set forth by such a cumulative investigation. While Applicants have included Hela cells that have not been treated with EMD there are no experiments implementing the non-cancerous cell types.

Furthermore, Applicants' claims include the use of "enamel matrix derivatives". This group is inclusive of enamelines, amelogenins, non-amelogenins, as well as a host of other enamel substances. It is not clear which substances should be considered derivatives capable of inducing apoptosis. Can enamel substances, such as proline-rich non-amelogenins and tuftelins, for example be expected to act in the same manner yielding the same result? Applicants' specification has not evidenced the use of possible enamel derivative combinations in a method for treating epithelially derived malignant or benign neoplasms *in vivo* or *in vitro*.

For the reasons set forth and in Paper #8 paragraph 5 the rejection is maintained. It would require undue experimentation of one of skill in the art to perform this broadly claimed method on an almost endless number of cancers of many, many different types.

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5. The rejection of claims 28-46 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained.

a. Claims 28-41 and 43 are vague and indefinite in the recitation "enamel substance" as the metes and bounds of the claim cannot be determined. Applicants argue that the term is clearly defined in the application. This is found unpersuasive. As stated in the previous office action a number of items are regarded as enamel substances. This collective term encompasses derivatives and other proteins. As presented in the specification there is a huge range of enamel substances, such as amelogenins, non-amelogenins and proline-rich non-amelogenins. The claims containing this term must be definite as to allow the comparison with the available art and clear for the public to determine what the claims encompass.

b. The recitation "...an active enamel substance." in claims 28-41 and 43 is vague and indefinite. Applicants argument has been presented above in section a. This argument is found unpersuasive. It is not clear if Applicants mean that active enamel substances are to possess the property of inducing apoptosis. Can this term be bestowed on all of the enamel substances?

c. Claims 30, 31 and 46 are vague and indefinite in the recitations "derivatives", "derivatives thereof" and "mixtures thereof". Applicants argue that the disclosure clearly describes derivatives and mixtures. Applicants have not set forth specific combinations of all the enamel substances, combinations, percentages of the

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different substances to make up such undefined derivatives and mixtures. Hence, the metes and the bounds of the claims are still unclear.

Conclusion

6. Claims 28-46 are free of the art.
7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Alana M. Harris, Ph.D.
Patent Examiner, Group 1642
December 22, 2001


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